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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,454	09/26/2003	Stephen Gregory Thomas	0623.0970001/LBB/SJE	5510

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/670,454	THOMAS ET AL.	
	Examiner	Art Unit	
	Stuart F. Baum	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-45* is/are pending in the application.

4a) Of the above claim(s) *28-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24 and 36-45* is/are rejected.

7)☒ Claim(s) *25-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/719,108.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 22-45 are pending.

2. Applicant's election with traverse of Group I, claims 25-27, including SEQ ID NO:1 encoding SEQ ID NO:2, in the reply filed on 8/12/2005 is acknowledged. The traversal is on the ground(s) that each of the four restriction groups are classified in the same class and subclass, they are all joined by at least one generic claim and the claimed sequences were not similarly restricted in the parent application and it would not be a burden to examine the claims together (first page of "Reply", 2nd paragraph).

This is not found persuasive because sequences may be classified in the same class and subclass, and may be dependent on the same generic independent claim, but while the search of the prior art for one group may overlap with that of another, they are not co-extensive of each other and thus would be a burden on the Office. Lastly, the Office contends that each case is examined on the basis of its own merits.

The requirement is still deemed proper and is therefore made FINAL.

Claims 28-35 are withdrawn from consideration for being drawn to non-elected inventions.

Claims 22-24 and 36-45 are linking claims.

3. Claims 22-27 and 36-45, to the extent they are drawn to SEQ ID NO:1 encoding SEQ ID NO:2, are examined in the present office action.

Oath and Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: Applicants have listed incorrectly the filing date of application 09/719,108 as December 8, 2000. The Office records indicate the correct filing date is May 25, 2001. In addition, Applicants have listed incorrectly the filing date of international application 9815404.0 as June 15, 1998. The Office records indicate the correct filing date is July 15, 1998. Correction is requested.

Application Data Sheet

5. The filing date for application 09/719,108, as discussed above, is also incorrectly listed in the Application Data Sheet.

Priority

6. The first paragraph of the specification incorrectly lists the filing date for application 09/719,108 as December 8, 2000. In addition, Applicant is requested to include the patent number of allowed application 09/719,108.

Information Disclosure Statement

7. Only the titles listed in the International Search Report have been considered. The recitation "International Search Report for PCT/GB99/01857" is not appropriate for printing on the front of a patent.

Document JP 9000069 was not considered because an English language translation was not supplied.

Written Description

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 22-24 and 36-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant cell transformed with a vector comprising a nucleic acid encoding a plant polypeptide having gibberellin 2-oxidase activity, or wherein the polypeptide is from Phaseolus or Arabidopsis, or wherein the polypeptide is from Phaseolus coccineus or Arabidopsis thaliana, or wherein the nucleic acid is operably linked to a promoter, or a transgenic plant or part grown from said plant cell.

Applicants disclose "Since the new enzyme of the present invention catalyses both the β-hydroxylation and further oxidation of the substituted hydroxyl group to a ketone group at C-2, the enzyme has been termed a 'GA 2-oxidase'" (page 4, lines 6-9). Applicants disclose a cDNA clone encoding a GA 2β-hydroxylase was isolated from Phaseolus coccineus embryos by screening a cDNA library for expression of a functional enzyme (page 19, lines 24-28). A putative GA 2β-hydroxylase clone was designated as 2B27 (page 21, line 8). Applicants disclose the P. coccineus 2-oxidase cDNA clone pc-2boh.dna as PcGA2ox1 whose nucleotide sequence is set forth in SEQ ID NO:1, with the coding region at residues 68-1063 of SEQ ID NO:1, encoding the amino acid sequence of SEQ ID NO:2 (page 18, lines 17-19).

The Applicants do not identify essential regions of gibberellin 2-oxidase enzymes encoded by SEQ ID NO:1, nor do Applicants describe a representative number of sequences encoding any GA 2-oxidase enzyme with the same function as the protein encoded by SEQ ID NO:1.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural

features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a GA 2-oxidase enzyme falling within the scope of the claimed genus of polynucleotides. Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the GA 2-oxidase enzyme, it remains unclear what features identify a Phaseolus GA 2-oxidase enzyme. Since the genus of GA 2-oxidase enzymes has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Scope of Enablement

9. Claims 22-24 and 36-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a plant or plant cell transformed with a vector comprising SEQ ID NO:1 encoding SEQ ID NO:2, or a nucleic acid molecule encoding SEQ ID NO:2, wherein the nucleic acid molecule is operably linked to a promoter, wherein the transformed plant has a reduced height, and a delayed or absent inflorescence development which can be reversed by the application of GA_3, does not reasonably provide enablement for a plant or plant cell comprising a vector comprising any nucleic acid encoding any protein having gibberellin 2-

oxidase enzyme activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to a plant cell transformed with a vector comprising a nucleic acid encoding a plant polypeptide having gibberellin 2-oxidase activity wherein said polypeptide inhibits growth in a plant grown from said transformed plant cell, or wherein the polypeptide is from Phaseolus or Arabidopsis, or wherein the polypeptide is from Phaseolus coccineus or Arabidopsis thaliana, or wherein the nucleic acid is operably linked to a promoter, or a transgenic plant or part grown from said plant cell, or wherein the nucleic acid is operably linked to a promoter, or wherein the promoter is a constitutive promoter or a promoter specific for expression in a particular cell, or wherein said inhibition of plant growth reduces bolting; or plant material capable of proliferation obtained from said plant.

Applicants disclose "Since the new enzyme of the present invention catalyses both the β-hydroxylation and further oxidation of the substituted hydroxyl group to a ketone group at C-2,

the enzyme has been termed a 'GA 2-oxidase'" (page 4, lines 6-9). Applicants disclose a cDNA clone encoding a GA 2β-hydroxylase was isolated from Phaseolus coccineus embryos by screening a cDNA library for expression of a functional enzyme (page 19, lines 24-28). A putative GA 2β-hydroxylase clone was designated as 2B27 (page 21, line 8). Applicants disclose the P. coccineus 2-oxidase cDNA clone pc-2boh.dna as PcGA2ox1 whose nucleotide sequence is set forth in SEQ ID NO:1, with the coding region at residues 68-1063 of SEQ ID NO:1, encoding the amino acid sequence of SEQ ID NO:2 (page 18, lines 17-19). Applicants disclose Arabidopsis plants and Nicotiana sylvestris plants transformed with said nucleic acid operably linked to the 35S promoter, exhibited some degree of dwarfing and disruption of flower development (page 26 lines 4-28).

The state-of-the-art teaches not all GA 2-oxidase genes have the same catalytic activity. Thomas et al (1999, PNAS 96:4698-4703, listed in IDS) teach the catalytic acitivity for all GA 2-oxidase enzymes is not all the same. Thomas et al teach that GA_{51}- catabolite is produced by PcGA2ox1 and AtGA2ox2 but not by AtGA2ox1 and AtGA2ox3, (page 4702, left column, first paragraph). Thomas et al continue by disclosing that GA_{15} was converted to a single product by PcGA2ox1 and AtGA2ox2 and not by the other two GA 2-oxidases (page 4702, left column, 2nd paragraph). The state-of-the-art also teaches transforming plants with nucleic acids encoding GA 2-oxidase proteins produces unexpected results. Biemelt et al (2004, Plant Physiology 135:254-265) disclose Arabidopsis plants transformed with a nucleic acid from Arabidipsis encoding the AtGA2-ox protein, not only produced dwarf plants, but said plants also exhibited a down regulation of lignin biosynthetic genes (abstract) and a reduction in plant biomass (page 258, left column, 2nd full paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

Applicants' claims are drawn to a plant cell which has been transformed with a vector comprising a nucleic acid, but Applicants do not indicate that the nucleic acid is operably linked to a promoter. Transforming plants with a nucleic acid that is just a coding region of a protein, will not produce the desired phenotype, because the nucleic acid will not be expressed in the desired cell, tissue, or organ at the correct developmental time. Expression of the nucleic acid will depend where in the genome the nucleic acid is integrated. To be expressed correctly, the nucleic acid must integrate in frame, and within a region that is within close proximity to a promoter, a promoter whose spatial and temporal expression matches Applicants' needs.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a plant with a reduced height and wherein the expressed protein exhibits gibberellin 2-oxidase activity.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

10. Claims 43-45 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 43-45 are drawn to part of a transgenic plant, a plant material capable of proliferation, or wherein said plant material is seeds, embryos, egg cells, or zygotes. The Office interprets "part of a transgenic plant" to read on seeds, embryos, egg cells, or zygotes. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the above recited parts or plant material having at least a single copy of the transgene and one quarter of the above recited parts or plant material would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed above recited parts or plant material, it is unclear whether the claimed above recited parts or plant material would be distinguishable from above recited parts or plant material that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy , Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the above recited parts or plant material comprise the construct that was introduced into the parent would overcome the rejection.

11. Claims 22-27 and 36-45 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a plant cell or plant transformed with a vector comprising a nucleic acid which encodes a plant polypeptide having gibberellin 2-oxidase activity, or wherein the nucleic acid comprises SEQ ID NO:1 or comprises a nucleic acid encoding SEQ ID NO:2.

12. Claims 25-27 are objected to, but would be allowable if re-written in independent form including all the limitations recited in the claims from which they depend.

13. Claims 22-24, and 36-45 are not allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
February 27, 2006